



Participation Information and Consent Form

Chief Investigator: Professor Nick Titov

PARTICIPANT INFORMATION AND CONSENT FORM

Testing the ‘Things You Do Model’. Do our daily actions affect our mental health?

You are invited to participate in this study of the ‘Things You Do’ model of psychological health. The ‘Things You Do’ is a list of actions we can take each day that are associated with better mental health and fewer symptoms of anxiety and depression. The ‘Things You Do Model’ of psychological health proposes that restricting these actions will lead to an increase in symptoms, while increasing these actions will lead to better mental health.

This research is being conducted by:

- Professor Nick Titov, School of Psychological Sciences, Macquarie University
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, Macquarie University
- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University
- Assoc Professor Lauren Staples, Database Manager / Research Fellow, Macquarie University
- Professor Dr Olav Nielssen, MindSpot Clinic, Macquarie University

Before you decide to participate in this research trial, it is important for you to understand why the research is being done and what participation will involve. Please take the time to read the following information carefully and discuss with others, including your primary physician or specialist, as needed.

PLEASE NOTE: You are also welcome to contact Professor Nick Titov via phone (0488 991 122) or email (contact@ecentreclinic.org) regarding this research or your participation at any point.

1. What is the purpose of this research trial?

The purpose of this research is to test the ‘Things You Do Model’ of mental health. This model has shown that doing five types of actions each week helps reduce symptoms of anxiety and depression. We now want to test three additional questions. First, whether restricting these actions also leads to an increase in symptoms and then how increasing these actions reduces symptoms? Second, whether people will actually restrict doing the things which are good for their mental health. Third, we also want to better understand people’s experiences as they restrict and increase their daily actions. This information will help us develop insights into how people develop and then recover from symptoms of anxiety and depression. In turn, this information may help create mental health prevention and self-help programs for the Australian people.

2. Background to the trial

Our research tells us that doing the actions listed on the ‘Things You Do’ Questionnaire is strongly linked with positive mental health. Understanding whether the opposite is true (that is, does restricting the actions lead to poorer mental health?) provides another important test of this model of psychological health. This may seem like an obvious question, but to our knowledge, has never been scientifically tested. This is an important question - information about what may trigger symptoms of anxiety and depression could help mental health professionals to better differentiate between clinical depression and distressing reactions to difficult life circumstances, leading to better treatment recommendations.



Understanding how peoples' daily actions and activities are related to psychological health may also lead to the development of more effective prevention programs and public health interventions. For example, such information could be used to help people recognise their own 'tipping points', beyond which their mental health either increases or reduces. This is particularly important in Australia where more people are experiencing the impacts of major natural disasters, such as floods and bushfires, after which engagement with usual routines and actions is often restricted.

3. Who is eligible to participate in this research trial?

You are eligible to participate in this trial if:

- (1) You are 18 years or older
- (2) You are living in Australia

Currently, we cannot include people who:

- (1) Moderate or greater symptoms of anxiety or depression
- (2) Are not living in Australia
- (3) Are unable to read or understand English

4. What does this research trial involve?

Once you have read this information sheet and have decided that you wish to participate, you can apply to participate in the 'Things You Do' on the eCentreClinic website (www.ecentreclinic.org). If you meet the study eligibility criteria you will receive a telephone call from a mental health clinician who will describe the study in more detail and answer any questions. Providing they confirm that you meet the eligibility criteria you will be invited to join the study as a research participant.

As a participant you will be asked to complete the following two Phases. Each Phase lasts 4 weeks, and you will begin with Phase 1:

- Phase 1 (Restriction Phase): Each week you will complete the 'Things You Do' questionnaire. You will be asked to **restrict** how often you do the actions listed in the questionnaire.
- Phase 2 (Expansion/Increase Phase): Each week you will complete the 'Things You Do' questionnaire. You will be asked to **increase** how often you do the actions listed in the questionnaire. You will also receive daily (Mon-Fri) text message reminders to do those things.

The total time of this study is 8 weeks, but we will contact you again 3 months later to ask you to complete a final set of questionnaires.

5. What else does this research trial involve?

Each week you will be asked to complete questionnaires about your mental health. These questionnaires are essential and will take about 10 to 15 mins to complete. They help us to evaluate the 'Things You Do Model' of psychological health and your own mental health.



6. How is this research being paid for?

There are no costs for participants in this research trial, and participants cannot be remunerated for their participation.

7. Will I benefit from participating in this research trial?

We expect that participating in this study will help you learn more about your mental health and the actions you can take each day to stay mentally healthy. We expect that you will learn more about your personal ‘tipping point’ of actions, that is, the point beyond which your mental health either increases or decreases. However, we cannot guarantee or promise that you will receive any benefit from participating.

8. Are there risks to participating in this research trial?

During Phase 1, the Restriction Phase, we expect that you may experience a small reduction in your mental health, that is, we expect you may experience a small increase in symptoms of anxiety and depression. However, in Phase 2, the Expansion/Increase Phase, we expect that you will experience an improvement in their mental health and any symptoms will decrease.

We expect these results because the ‘Things You Do Model’ is based on daily actions which we can choose to restrict or increase. Nonetheless, we will monitor your mental health each week, and you are welcome to contact us at any time with questions or concerns, and we will contact you if we notice any problems with your mental health. You also have the option of contacting us during Phase 1 to arrange an early transition to Phase 2 if you wish.

PLEASE NOTE: If you experience a significant deterioration in your mood or feel at risk of self-harm or become concerned about your health, **please contact us and we will assist you. You can also receive support by contacting services such as Beyond Blue, MindSpot, your GP or in an crisis, the emergency services on 000. We will provide contact details for these organisations before you start the study.**

9. What if I do not want to participate or I want to withdraw later?

Participation in this research trial is voluntary. It is up to you whether or not you decide to participate and your decision will not impact your relationship with the research investigators or their respective institutions. You can also choose to withdraw from the research at any time.

Importantly, any information and data you provide up until your withdrawal cannot be deleted or withdrawn consistent with the standard principles for health research.

10. How will my confidentiality be protected?

Confidentiality arrangements will follow Australian Law. Any identifiable information that is collected about you will remain entirely confidential and will not be disclosed without your express permission unless we are required to do so by law.

We will publish the results of this research and discuss these results at national and international scientific conferences; however, in any publication, information will be presented in such a way that you cannot be identified. Moreover, only the eCentreClinic will have access to your personal information.



PLEASE NOTE:

- We are required by law to report any instances where we become concerned about your personal safety or the personal safety of others, particularly children.
- We will communicate with you via the email and phone number you provide us. Please only provide us an email and phone number that is secure and it is suitable for us to use to send you information and contact you.

11. Can I see a copy of the published research?

You are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact Professor Nick Titov or the eCentreClinic (contact@ecentreclinic.org) to discuss this research and ask any questions you may have at any time.



PARTICIPANT CONSENT FORM

Testing the 'Things You Do Model'. Do our daily actions affect our mental health?

Once you have read this Participant Information and Consent form, you can click the 'consent' button to enrol in this research trial.

Importantly, by submitting an application, you consent to the points below:

1. You would like to participate in the 'Things You Do' research trial.
2. You have read the Participant Information Statement for the research trial.
3. You have the opportunity to raise any questions or concerns with us at any time.
4. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers, the eCentreClinic, or Macquarie University.
5. Research data gathered from the present research may be published in a de-identified format; that is, in an entirely anonymous format where individuals cannot be identified.
6. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement; however, all data would be in a de-identified format and all uses will be subject to approval from an Australian Human Research Ethics Committee.
7. You can raise any questions or concerns about this research project with Professor Nick Titov at the eCentreClinic (contact@ecentreclinic.org) at any time.

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Ethics Review Committee through the Director, Research Ethics and Integrity (telephone +61 2 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

REVOCATION OF CONSENT FORM

If at any time you wish to withdraw from this study, please contact the eCentreClinic by **emailing the text below back to contact@ecentreclinic.org**.

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the eCentreClinic or Macquarie University.